

K112000

OCT 26 2011



## 510(k) SUMMARY

### VITEK® 2 AST-ST Penicillin

#### 510(k) Submission Information:

Submitter's Name: bioMérieux, Inc.  
Address: 595 Anglum Road  
Hazelwood, MO 63042  
Contact Person: Jolyn Tenllado  
Director, Regulatory Affairs  
Phone Number: 314-731-8386  
Fax Number: 314-731-8689  
Date of Preparation: July 12<sup>th</sup>, 2011

#### B. Device Name:

Formal/Trade Name: VITEK® 2 *Streptococcus* Penicillin  
Classification Name: 21 CFR 866.1645  
Antimicrobial Susceptibility Test  
Product Code LON  
Common Name: VITEK® 2 AST-ST Penicillin

C. Predicate Device: VITEK® 2 AST-GP Amoxicillin for *S. pneumoniae* (K063597)

#### D. 510(k) Summary:

VITEK® 2 *Streptococcus* Penicillin is designed for antimicrobial susceptibility testing of *Streptococcus* species. VITEK® 2 *Streptococcus* Penicillin is a quantitative test intended for use with the VITEK® 2 and VITEK® 2 Compact Systems as a laboratory aid in the determination of *in vitro* susceptibility to antimicrobial agents. Penicillin has been shown to be active against most strains of the microorganism listed below, according to the FDA label for this antimicrobial.

#### Active *In Vitro* and in Clinical Infections against:

Beta hemolytic streptococci groups C and G  
*Streptococcus pyogenes*  
*Streptococcus agalactiae*  
*Streptococcus viridans* group  
*Streptococcus pneumoniae*

The VITEK® 2 Antimicrobial Susceptibility Test (AST) is intended to be used with the VITEK® 2 and VITEK® 2 Compact Systems for the automated quantitative or qualitative susceptibility testing of isolated colonies for the most clinically significant aerobic gram-negative bacilli, *Staphylococcus spp.*, *Enterococcus spp.*, *Streptococcus spp.* and clinically significant yeast.

#### bioMérieux, Inc.

595 Anglum Road, Hazelwood, Missouri 63042-2320, USA Phone: 314/731-8500 800/638-4835 Fax: 314/731-8700  
<http://www.biomerieux-usa.com> Page 256



bioMérieux, Inc.  
c/o Jolyn Tenllado  
Director, Regulatory Affairs  
595 Anglum Road  
Hazelwood, Missouri 63042-2320

OCT 26 2011

Re: K112000

Trade/Device Name: VITEK® 2 *Streptococcus* Penicillin ( $\leq 0.06 - \geq 8$  µg/mL)

Regulation Number: 21 CFR 866.1645

Regulation Name: short-term Antimicrobial Susceptibility Test System

Regulatory Class: Class II

Product Code: LON

Dated: October 19, 2011

Received: October 20, 2011

Dear Ms. Tenllado:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

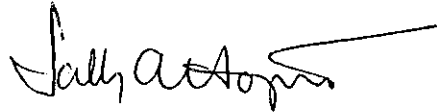
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket

notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Sally A. Hojvat", with a long horizontal flourish extending to the right.

Sally A. Hojvat, M.Sc., Ph.D.  
Director  
Division of Microbiology Devices  
Office of *In Vitro* Diagnostic Device  
Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K112000

Device Name: VITEK® 2 *Streptococcus* Penicillin  
( $\leq 0.06 - \geq 8$  µg/mL)

### Indications For Use:

VITEK® 2 *Streptococcus* Penicillin is designed for antimicrobial susceptibility testing of *Streptococcus* species. VITEK® 2 *Streptococcus* Penicillin is a quantitative test intended for use with the VITEK® 2 and VITEK® 2 Compact Systems as a laboratory aid in the determination of *in vitro* susceptibility to antimicrobial agents. Penicillin has been shown to be active against most strains of the microorganism listed below, according to the FDA label for this antimicrobial.

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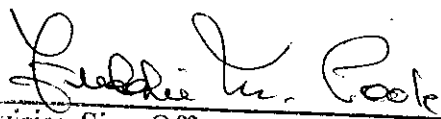
Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

  
Division Sign-Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k) K112000

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